



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/811,916 | 03/30/2004 | Yasuyuki Numajiri | 00684.003621. | 3181 |

5514 7590 08/10/2010
FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

| |
|----------|
| EXAMINER |
|----------|

BOWERS, NATHAN ANDREW

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1797

| | |
|-----------|---------------|
| MAIL DATE | DELIVERY MODE |
|-----------|---------------|

08/10/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/811,916 | Applicant(s) NUMAJIRI ET AL. | |
| | Examiner NATHAN A. BOWERS | Art Unit 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 May 2010 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

Art Unit: 1797

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1, 4, 5, 8 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin (US 20050272169) in view of Schnipelsky (US 5229297) and Clark (US 6656428).

With respect to claim 1, Griffin discloses a biochemical cartridge comprising a reaction portion (Figure 1:14) that includes a plurality of chambers (Figure 1:16, 18, 17, 20) and a plurality of channels (Figure 1:15). A solution storage portion (Figure 1:12) is isolated and separated above the reaction portion. A penetrable portioning member (Figure 1:13) is disposed between the solution storage portion and the reaction portion so as to move the solution from the solution storage portion to the chamber of the reaction portion. This is disclosed in paragraphs [0009]-[0012] and [0084]-[0094]. Paragraphs [0034] and [0051] state that the solution storage portion and the reaction portion are constructed as independent articles that are brought together only at a time when the apparatus is in use. Paragraph [0044] states that the portions are reversibly coupled together using a mechanical clamping mechanism. Paragraphs [0030] and [0088] indicate that any one of the many chambers of the reaction portion may or may not contain a dried reagent. Griffin further discloses in paragraphs [0085] and [0086]

Art Unit: 1797

that the reaction portion (14) includes a supply port (17) facing the storage portion (12) but not covered by the storage portion during use. The port opening (23) is unobstructed by a flap means (24) at the time of use.

However, Griffin does not expressly state that the reaction portion includes a port at a side surface for permitting access to the chambers. Although Griffin does indicate in paragraph [0011] that fluidic ports may be positioned in either the reaction portion or the solution storage portion, Griffin does not expressly describe a port positioned at a reaction portion side surface.

Schnipelsky discloses a biochemical reaction cartridge comprising a reaction portion (Figure 7:10B) holding a plurality of solution storage portions (Figure 7:30B, 32B, 34B, 36B, 38B) and a reaction chamber (Figure 7:40B). This is disclosed in column 9, line 62 to column 10, line 46. Schnipelsky states that fluids are moved to the reaction chamber from the solution storage portions. Schnipelsky additionally states that fluid is also moved to the reaction chamber through a port (Figure 7:22A) constructed at the sidewall of the reaction chamber.

Griffin and Schnipelsky are analogous art because they are from the same field of endeavor regarding biochemical reaction cartridges.

At the time of the invention, it would have been obvious to form a fluid port along the exterior walls of the Griffin reaction portion. Griffin contemplates doing exactly this in paragraph [0011] stating “an inlet in either the [reaction portion] or the [solution storage portion] into which a sample to be analyzed can, in use, be placed.”

Schnipelsky further is provided as evidence that it is known in the art to construct a fluid

Art Unit: 1797

port along the sidewall of a reaction portion. Schnipelsky teaches that fluid moves to the reaction chamber from not only solution storage chambers, but also from a fluid port fabricated at the sidewall of a reaction portion. Accordingly, one of ordinary skill in the art would have been motivated to move fluid to the Griffin reaction chamber simultaneously from the disclosed plurality of solution storage portions, as well as from fluid ports located along the sidewalls of the Griffin reaction portion.

The combination of Griffin and Schipelsky still differs from Applicant's claimed invention. Although Griffin describes the use of needles (Figure 3:145) to puncture the partition member, Griffin does not expressly state that the needles seals the solution storage portion when moved from a first pushing location to a second pushing location.

Clark discloses a biochemical reaction cartridge comprising a solution storage portion (Figure 4:8) situated above a reaction portion (Figure 4:14). A tool needle (Figure 4:24) is used to puncture a partitioning member (Figure 4:26) when moved to a first position. This is described in column 26, lines 49-64. Clark additionally states that the needle includes a sealant layer that provides a barrier to seal the reaction portion when the needle is moved to a second position. See Figure 4 and 5B.

Griffin and Clark are analogous art because they are from the same field of endeavor regarding biochemical reaction cartridges.

At the time of the invention, it would have been obvious to ensure that the needles 145 disclosed by Griffin are capable of sealing holes created in the partition membrane and reaction portion when the needles are pushed all the way through the

Art Unit: 1797

partition member to a second position. As evidenced by Clark, the use of a sealant layer to provide a barrier around a needle when transferring a reaction solution through a partitioning membrane is known in the art. One of ordinary skill would have especially found this to be an obvious modification of Griffin because in paragraph [0109] Griffin expresses a desire for to creation of a fluid tight seal about the needle upon its actuation. One of ordinary skill would have recognized that contamination would be avoided by allowing the needle to seal the puncture hole after the delivery of the reaction fluid.

With respect to claims 4 and 5, Griffin, Schnipelsky and Clark disclose the apparatus set forth in claim 3 as set forth in the 35 U.S.C. 103 rejections above. Griffin additionally teaches in paragraphs [0096] and [0097] that the needles (Figure 3:145) are moved using a pressing rod (Figure 3:130). Griffin does not expressly disclose that multiple pressing rods of differing lengths are used to determine how far the needles are allowed to penetrate into the partition member (Figure 3:113). However, simple changes to the shape and size of a structure are not considered to be patentable distinctions over the prior art. At the time of the invention, it would have been obvious to utilize pressing rods that are of a suitable length. The length of the pressing rods is considered to be a result effective variable that is optimized through routine experimentation. See MPEP 2144.04 and 2144.05.

With respect to claim 8, Griffin, Schnipelsky and Clark disclose the invention as set forth in the rejections above. Additionally, Griffin teaches that solutions contained in a plurality of chambers (Figure 1:22) on the solution storage portion (Figure 1:12) are independently moved through the partition member (Figure 1:13) and collected in corresponding chambers (Figure 1:116) of the reaction portion (Figure 1:14). Each solution is moved via channels (Figure 1:15) to a central reaction area (Figure 1:18) in order to facilitate the detection of analytes. Griffin, however, teaches that the same partition member is punctured multiple times. Griffin does not indicate that each solution storage portion chamber is associated with a separate partition member.

At the time of the invention, it would have been obvious to divide the comprehensive partition member disclosed Griffin into a plurality of smaller partition members each selectively associated with a specific solution storage chamber. This would have been beneficial because it would have ensured that defects in one partitioning area do not affect the operation of the device in other partitioning areas. The separation of a large structure into a plurality of smaller structures characterized by identical properties is generally not considered to be a patentable improvement over the prior art. See MPEP 2144.04.

With respect to claim 11, Griffin, Schnipelsky and Clark disclose the combination as previously described above. Griffin discloses a biochemical treatment apparatus comprising an accommodation unit in which a biochemical reaction cartridge including a reaction portion (Figure 1:14) and a solution storage portion (Figure 1:12) are mounted.

Art Unit: 1797

The reaction and solution storage portions each have a plurality of chambers that correspond to one another such that reagents from the storage portion are collected in the reaction portion following the activation of a driving means (Figure 3:145). The driving means penetrates a partition member (Figure 1:13) of the biochemical reaction cartridge mounted in the accommodation unit. Various reaction treatment means are provided for causing the rupture of the partition member. The partition member can be broken due to the pumping of excess fluids to the chambers of the solution storage portion, or through the mechanical activation of a plunger (Figure 3:130). This is described in paragraphs [0084]-[0098]. Paragraph [0090] states that a control means in the form of a microprocessor is provided for regulating the motion of the driving means.

However, Griffin does not expressly state that the reaction portion includes a port at a side surface for permitting access to the chambers. Although Griffin does indicate in paragraph [0011] that fluidic ports may be positioned in either the reaction portion or the solution storage portion, Griffin does not expressly describe a port positioned at a reaction portion side surface.

Schnipelsky discloses a biochemical reaction cartridge comprising a reaction portion (Figure 7:10B) holding a plurality of solution storage portions (Figure 7:30B, 32B, 34B, 36B, 38B) and a reaction chamber (Figure 7:40B). This is disclosed in column 9, line 62 to column 10, line 46. Schnipelsky states that fluids are moved to the reaction chamber from the solution storage portions. Schnipelsky additionally states that fluid is also moved to the reaction chamber through a port (Figure 7:22A) constructed at the sidewall of the reaction chamber.

Griffin and Schnipelsky are analogous art because they are from the same field of endeavor regarding biochemical reaction cartridges.

At the time of the invention, it would have been obvious to form a fluid port along the exterior walls of the Griffin reaction portion. Griffin contemplates doing exactly this in paragraph [0011] stating “an inlet in either the [reaction portion] or the [solution storage portion] into which a sample to be analyzed can, in use, be placed.”

Schnipelsky further is provided as evidence that it is known in the art to construct a fluid port along the sidewall of a reaction portion. Schnipelsky teaches that fluid moves to the reaction chamber from not only solution storage chambers, but also from a fluid port fabricated at the sidewall of a reaction portion. Accordingly, one of ordinary skill in the art would have been motivated to move fluid to the Griffin reaction chamber simultaneously from the disclosed plurality of solution storage portions, as well as from fluid ports located along the sidewalls of the Griffin reaction portion.

With respect to claim 12, Griffin, Schnipelsky and Clark disclose the apparatus in claim 11 wherein the penetration means is provided in the biochemical reaction cartridge. Figures 3-21 of Griffin clearly show that a piercing pin is provided within the cartridge.

With respect to claim 13, Griffin, Schnipelsky and Clark disclose the apparatus in claim 11 wherein the penetration means is provided to the biochemical treatment apparatus. In paragraph [0014], Griffin states that the penetration means is provided in

Art Unit: 1797

the form of extra fluid that is pumped to the chambers of the solution storage portion via the reaction treatment means.

2) Claims 6, 7, 9, 10, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin (US 20050272169) in view of Schnipelsky (US 5229297) and Clark (US 6656428) as applied to claims 1, 8 and 11, and further in view of Vann (US 6432719).

Griffin, Schnipelsky and Clark disclose the apparatus and method set forth in claims 1, 8 and 11 as set forth in the 35 U.S.C. 103 rejections above. In paragraph [0090], Griffin teaches that the treatment sequence including the order of penetration of the partition member is regulated using a microprocessor controller. Griffin, however, does not indicate that the controller is capable of operating based on information provided by identification codes placed on the cartridge.

Vann discloses a biochemical reaction cartridge comprising a reaction portion formed by a base plate (Figure 1:22) and a frame assembly (Figure 1:46). The frame assembly is divided in such a way to provide a plurality of reaction chambers (Figure 1:32). A solution storage portion (Figure 1:42) is positioned over the reaction portion in order to move fluids stored within the storage portion to the chambers of the reaction portion using a partition member (Figure 7:278, 280). Specifically, Vann discloses in column 6, line 65 to column 8, line 11, column 10, lines 7-49 and column 11, lines 46-64 that a magnetic pinch valve is used to regulate the flow of fluid to the reaction portion from the storage portion. Operation of the cartridge is regulated by a control computer

Art Unit: 1797

that receives information regarding the contents of the solution storage containers via identification codes printed on the solution storage containers.

Griffin and Vann are analogous art because they are from the same field of endeavor regarding biochemical reaction cartridges.

At the time of the invention, it would have been obvious to provide the cartridge disclosed by Griffin with an identification code that is reflective of the contents of each of the solution storage portion chambers. As evidenced by Vann, it is known in the art to use bar codes in an automated system to ensure that reagents are added to a reaction chamber in the correct order. The use of identification codes is effective since it allows the user to quickly determine the contents of a specific storage container and proceed according to the predetermined treatment sequence.

Response to Arguments

Applicant's arguments filed 17 May 2010 with respect to the 35 U.S.C. 103 rejections involving the combination of Griffin and Schnipelsky have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration, a new ground of rejection is made in view of the combination of Griffin, Schnipelsky and Clark.

Clark more clearly addresses the deficiencies of Griffin by disclosing the use of a needle to puncture a partition membrane, and subsequently seal the created hole when the needle is moved to a second position. Clark discloses a sealant layer (See Figure

Art Unit: 1797

4) provided around the needle that is capable of sealing the ruptured partition membrane when the needle is fully depressed. This is illustrated in Figure 5B.

Conclusion

This is a non-final rejection.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nathan A Bowers/
Examiner, Art Unit 1797